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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/002,485	12/31/97	LAL P	PF-0459US

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EXAMINER	
SAOUD,C	
ART UNIT	**PAPER NUMBER**
1646	12

DATE MAILED: 06/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/002,485	LAL et al.
Examiner	**Group Art Unit**
Christine Saoud	1646

☒ Responsive to communication(s) filed on *May 14, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-23* is/are pending in the application.

Of the above, claim(s) *1 and 15-23* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4, 11*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II (claims 2-14, SEQ ID NO:25 and 102) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the search of Group VIII would not pose a burden because the searches for Groups II and VIII would overlap. This is not found persuasive because Groups II and VIII are properly restricted because burden of search can be established by separate classification as was provided in paper #9.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1 and 15-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Information Disclosure Statement

3. Applicant should note that several of the items provided on the IDS of paper #4 (4/6/98) will not be printed on any patent that results from the instant application. This is because they are in a format which is not acceptable for printing. For example, item 1 is to a database site, which does not have a date. Item 52 is a list of GenBank accession numbers without any corresponding dates. This information has been considered since it was submitted on the IDS, however, this information cannot be printed on the face of any patent resulting from the instant application.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention ***to which the claims are directed.***

Claim Objections

5. Claims 2-8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the instant case, the nucleic acid claims could be infringed without infringing the claims from which it depends, i.e. the protein claims. Therefore, they are improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 2-14 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the signal peptide-containing protein described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins; in the instant case, containing a signal peptide. There is little doubt that, after complete characterization, this protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the claimed DNA encoding a signal peptide-containing protein can be used "in the diagnosis, treatment and prevention of cancer and immunological disorders" (see page 14 of the specification). Until some actual and specific significance can be attributed to the protein of SEQ ID NO:25, encoded by the DNA of SEQ ID NO:102, the instant invention is incomplete. The DNA of the instant invention and the protein encoded thereby are compounds which contain signal peptides. The specification indicates that proteins which contain signal peptides include G-protein coupled receptors, tetraspanins, MPs, lectins, protein kinases, protein phosphatases, protein phosphatase inhibitors, cyclic nucleotides, phospholipases, nucleotide cyclases, chemokines, growth and differentiation factors, proteolytic enzymes, zinc proteases, guanosine triphosphate-binding proteins, ion channels, ion pumps, membrane proteins, amino acid transporters, proton-coupled transporters, hormones, neuropeptides, and transcription factors (see pages 1-13 of the specification). At page 47 of the specification, the protein of SEQ ID NO:25 is indicated to share 28% sequence identity with mouse beta chemokine, however, this is not a disclosure of how to use the protein (or the DNA encoding it) because chemokines are a broad

class of proteins which have divergent biological activity which cannot be predicted based on amino acid sequence information alone. In the absence of a knowledge of what the protein of SEQ ID NO:25 is, or the biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for claimed DNA encoding the protein of SEQ ID NO:25 then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

8. Claims 2-14 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.

Claim Rejections - 35 USC § 112

9. Claims 5 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to polynucleotide variants having at least 90% sequence identity to a particular sequence identifier. In making a determination of whether the application

complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO:25. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO:102. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are directed to polynucleotide variants. First, the claims are not limited to a DNA encoding a protein with a specific amino acid sequence. The broadest claim only requires the polynucleotide be a variant which shares at least 90% sequence identity to a given sequence. The specification only describes a single polypeptide from a human and fails to teach or describe any other polypeptide which could be a variant. The breadth of the claims is such that the claims encompass polynucleotides from other species and variant polynucleotides. There is a lack of guidance or teaching regarding structure and function of the polypeptide because there is no disclosure of the function of the polypeptide.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed.

With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polypeptide of SEQ ID NO:25 and the polynucleotide of SEQ ID NO:102. The specification does not provide a complete structure of variant polynucleotides which have at least 90% sequence identity to the disclosed sequences. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus because the claims are directed to a polynucleotide variant, which encompasses different species and variants and the specification teaches one embodiment. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are directed to polynucleotides which hybridize under "stringent conditions". However, the metes and bounds of "stringent conditions" cannot be determined from the claim or the instant specification. There are a multitude of conditions that are used by the skilled artisan which could be considered, which range from low stringency to high stringency, all of which depend on a number of variables in the hybridization process. Without knowing which set of conditions are intended by the claims, one would not be able to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 2-8, 10, 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Wei et al. (U.S. Pat. No. 5,981,231).

Wei et al. teach a DNA of SEQ ID NO:1 encoding a protein of SEQ ID NO:2. The protein of SEQ ID NO:2 is approximately 98% identical to that of SEQ ID NO:25 of the instant application. The DNA of SEQ ID NO:1 is approximately 99.2% identical to that of SEQ ID NO:102. Wei et al. teach compositions, isolated DNA, complementary DNA, vectors, host cells,

and recombinant methods of protein production (see claims, for example). Therefore, the instant claims are anticipated by the DNA of Wei et al.

Conclusion

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 7, 2000

CHRISTINE SAOUD
PATENT EXAMINER
Christine Saoud